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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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08/249,689

05/26/1994

PAUL R. SCHIMMEL

MIT5261

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7590

06/10/2002

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EXAMINER

BRUSCA, JOHN S

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 06/10/2002

54

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

08/249,689

Applicant(s)

SCHIMMEL, PAUL R.

Examiner

John S. Brusca

Art Unit

1631

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 April 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☒ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

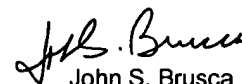
Claim(s) allowed: 1,3-10,14-16 and 20.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 11-13, 17-19, 21.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
John S. Brusca  
Primary Examiner  
Art Unit: 1631

Continuation of 5. does NOT place the application in condition for allowance because: The applicant's arguments presented in the response and declarations filed 11 April 2002 are not persuasive. The declarations of Julius Rebek Jr. and James R. Williamson provide discussion of RNA minor groove structures, and state that a molecule that binds to a site in a minor groove of RNA would have a structure comprising hydrogen-bond-forming groups positioned to interact with hydrogen-bond-forming groups of the RNA minor groove site in question. The declarations further state that the binding molecule must have a structure that further satisfies the steric constraints of the minor groove site. The declarations do not point to further description of the structure of the claimed compounds in the specification. The Williamson declaration additionally discusses ribosomal protein S15 which binds to an RNA minor groove. However, the data concerning S15 was not in the specification at the time of filing, and does not address the merits of the question of whether the claimed invention is supported by the description in the instant specification. Furthermore, the S15 data was not published until 2000, approximately ten years after the effective filing date of the instant application. Finally S15 does not inhibit the function of an RNA molecule as in the claimed invention.

The applicant's response states that the specification describes the claimed composition by structural properties. The structural properties pointed to by the applicants are structures that form hydrogen bonds with the critical region of the targeted RNA molecules. and further fit within the constraints of the minor groove of the critical region. However, the specification only describes inhibitory molecules with a function of forming hydrogen bonds and fitting within the steric constraints of a critical site of an RNA minor groove. Such a description is considered by the applicants to be a description of the structure of the claimed molecules, but upon review is it considered to be a description of a function of a structure rather than a description of a structure. While it is true that the described functions of the claimed molecules are determined by the structure of the claimed molecules, it is also true that all functions of all molecules are determined by molecular structure. What is missing is the structure of the claimed molecules.

The requirements for an adequate written description are discussed in the below cited passage of the "Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1st Paragraph Written Description Requirement published in the Federal Register (Vol. 66, No. 4, 5 January 2001, pages 1099-1111, available at [www.uspto.gov](http://www.uspto.gov)).

The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art.<sup>13</sup> This problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function.<sup>14</sup> A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process

Because the specification does not provide a working example of the structure of a representative number of species of the claimed genus of compounds, the applicants may alternatively show satisfaction of the written description requirements by presenting a compelling argument that there exists an art-recognized correlation between structure and the claimed function. As discussed in the above passage from the guidelines, written description of the claimed molecules cannot be provided by functional descriptions unless there is an art-recognized correlation between the described function and a structure. The declarations provided by the applicants have provided evidence that one of skill in the art would understand the necessity for the claimed molecules to possess the function of forming hydrogen bonds and complying with steric restraints of a critical site of an RNA minor groove. However neither the declarations, the response, nor the specification provide evidence for an art-recognized correlation between the required functions and the structure of the claimed molecules. As such the description of the claimed molecules have not been described by a structural description or by showing of an art-recognized correlation between function and structure, and the rejection is maintained.